



**PATENT**  
Attorney Docket No. **FORS-08453**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: **Molly Accola, et al.**  
Serial No.: **10/713,653**  
Filed: **11/14/2003**  
Entitled: **CFTR Allele Detection Assays**

Group No.: **1634**  
Examiner: **Goldberg**

**INFORMATION DISCLOSURE  
STATEMENT TRANSMITTAL**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on 8-21-06.

By: 

Mary Ellen Waite

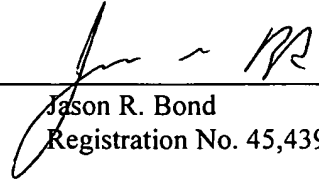
Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: August 21, 2006

  
Jason R. Bond  
Registration No. 45,439

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 305  
San Francisco, California 94105  
608/218-6900



**PATENT**  
Attorney Docket No. **FORS-08453**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Accola, *et al.*  
Serial No.: 10/713,653  
Filed: 11/14/03  
Entitled: **CFTR Allele Detection Assays**

Group No.: 1634  
Examiner: Goldberg

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)(1)(i)(A)**

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: August 21, 2006

By: 

Mary Ellen Waite

Sir or Madam:

The citations listed below may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

- U.S. Patent No. 5,614,402
- U.S. Patent No. 5,795,763
- U.S. Patent No. 5,843,669
- U.S. Patent No. 6,090,606
- U.S. Patent No. 6,090,543

- U.S. Patent No. 5,846,717
- U.S. Patent No. 5,985,557
- U.S. Patent No. 5,994,069
- U.S. Patent No. 6,001,567
- U.S. Patent No. 6,235,502
- U.S. Patent No. 6,194,149
- U.S. Patent No. 6,210,884
- U.S. Patent No. 6,183,960
- WO 98/23774
- WO 02/070755A2
- WO 01/90337A2
- WO 97/27214
- WO 98/42873
- WO9850403
- WO0198537
- Richards et al., Genetics in Medicine, 4:379-391 (2002)
- Makowski et al., Annals of Clinical 7 Laboratory Science, 33:243-250 (2003)
- Strom et al., Genetics in Medicine, 4:289-296 (2002)
- Heim, et al., Genetics in Medicine 3(3):168-176 (2001)
- Raman, et al., Pediatrics 109(1): E13 (2002)
- Dumur, et al., Hum Genet 97: 7-10 (1996)
- Grody, Cutting, et al., Genetics in Medicine 3(2):149-154 (2001)
- Grody and Desnick, Genetics in Medicine 3(2):87-90 (2001)
- Rosenstein and Cutting, Journal of Pediatrics 132(4): 589-595 (1999)
- LeGrys, Laboratory Medicine 33(1): 55-57 (2002)
- Wilson, et al., Journal of Pediatrics 132 (4): 596-599 (1998)
- Gregg, et al., Pediatrics 99(6): 819-824 (1997)
- Rock, et al., Pediatrics 85(6): 1001-1007 (1990)
- Kerem, et al., Science 245: 1073-1080 (1989)

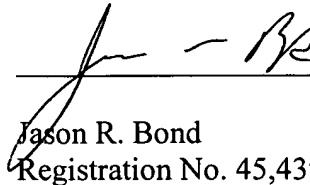
- Riordan, et al., Science 245: 1066-1073 (1989)
- Rommens, et al., Science 245: 1059-1065 (1989)
- Bobadilla, et al., Human Mutation 19: 575-606 (2002)
- Noone and Knowles, Respiratory Research 2(6):328-332 (2001)
- Rohlf, et al., Genetics in Medicine 4(5):319-323 (2002)
- Kiesewetter, et al., Nature Genetics 5(3): 274-278 (1993)
- Fujimura, Northrup et al. N Engl J Med., Jan 4, 322(1):61 (1990)
- Lyamichev et al., Nat. Biotech., 17:292 (1999)
- Hall et al., PNAS, USA, 97:8272 (2000)
- Reynaldo et al., J. Mol. Biol. 97: 511-520 (2000)

Applicants wish to bring to the examiners attention that we are not providing copies of US Patents as instructed under 37 CFR 1.98(a)(2).

As most of the World Publication references cited are over 400 pages, Applicants are providing the front page of these references only. Applicants will provide the entire documents upon Examiner request.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: August 21, 2006

  
\_\_\_\_\_  
Jason R. Bond  
Registration No. 45,439

MEDLEN & CARROLL, LLP  
101 Howard Street, Suite 350  
San Francisco, California 94105  
608/218-6900



PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 5

**Complete if Known**

Application Number	10/713,653
Filing Date	11/14/2003
First Named Inventor	Accola et al.
Art Unit	1634
Examiner Name	Goldberg, J.
Attorney Docket Number	FORS-08453

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1	US- 5,614,402	03/25/1997	Dahlberg et al.	whole document
	2	US- 5,795,763	08/18/1998	Dahlberg et al.	whole document
	3	US- 5,843,669	12/01/1998	Kaiser et al.	whole document
	4	US- 6,090,606	07/18/2000	Kaiser et al.	whole document
	5	US- 6,090,543	07/18/2000	Prudent et al.	whole document
	6	US- 5,846,717	12/08/1998	Brow et al.	whole document
	7	US- 5,985,557	11/16/1999	Prudent et al.	whole document
	8	US- 5,994,069	11/30/1999	Hall et al.	whole document
	9	US- 6,001,567	12/14/1999	Brow et al.	whole document
	10	US- 6,235,502	05/22/2001	Weissman et al.	whole document
	11	US- 6,194,149	02/27/2001	Neri et al.	whole document
	12	US- 6,210,884	04/03/2001	Lizardi	whole document
	13	US- 6,183,960	02/06/2001	Lizardi	whole document
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	14	WO 98/23774				
	15	WO 02/070755A2				
	16	WO 01/90337A2				
	17	WO 97/27214				
	18	WO 98/42873				
	19	WO9850403				

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

Sheet 2

of 5

A1

**Complete if Known**

Application Number	10/713 653
--------------------	------------

Filing Date	11/14/2003
-------------	------------

First Named Inventor	Accola et al.
----------------------	---------------

Art Unit	1634
----------	------

Examiner Name	Goldberg, J.
---------------	--------------

Attorney Docket Number	FORS-08453
------------------------	------------

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner  
Signature**

Date \_\_\_\_\_

**Considered**

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

**If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		<b>Complete if Known</b>			
		Application Number	10/713,653		
		Filing Date	11/14/2003		
		First Named Inventor	Accola et al.		
		Art Unit	1634		
		Examiner Name	Goldberg, J.		
Sheet	3	of	5	Attorney Docket Number	FORS-08453

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	21	Heim, et al., Genetics in Medicine 3(3):168-176 (2001)	
	22	Raman, et al., Pediatrics 109(1): E13 (2002)	
	23	Dumur, et al., Hum Genet 97: 7-10 (1996)	
	24	Grody, Cutting, et al., Genetics in Medicine 3(2):149-154 (2001)	
	25	Grody and Desnick, Genetics in Medicine 3(2):87-90 (2001)	
	26	Rosenstein and Cutting, Journal of Pediatrics 132(4): 589-595 (1998)	
	27	LeGrys, Laboratory Medicine 33(1): 55-57 (2002)	
	28	Wilson, et al., Journal of Pediatrics 132 (4): 596-599 (1998)	
	29	Gregg, et al., Pediatrics 99(6): 819-824 (1997)	
	30	Rock, et al., Pediatrics 85(6): 1001-1007 (1990)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/713,653
Filing Date	11/14/2003
First Named Inventor	.Accola et al.
Art Unit	1634
Examiner Name	Goldberg, J.
Attorney Docket Number	FORS-08453

Sheet 4

of

5

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	31	Kerem, et al., Science 245: 1073-1080 (1989)	
	32	Riordan, et al., Science 245: 1066-1073 (1989)	
	33	Rommens, et al., Science 245: 1059-1065 (1989)	
	34	Bobadilla, et al., Human Mutation 19: 575-606 (2002)	
	35	Noone and Knowles, Respiratory Research 2(6):328-332 (2001)	
	36	Rohlfs, et al., Genetics in Medicine 4(5):319-323 (2002))	
	37	Kiesewetter, et al., Nature Genetics 5(3): 274-278 (1993)	
	38	Fujimura, Northrup et al. N Engl J Med., Jan 4, 322(1):61 (1990)	
	39	Lyamichev et al., Nat. Biotech., 17:292 (1999)	
	40	Hall et al., PNAS, USA, 97:8272 (2000)	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	10/606,577
		Filing Date	06/26/2006
		First Named Inventor	Accola et al.
		Art Unit	1634
		Examiner Name	Goldberg, J.
Sheet 5	of 5	Attorney Docket Number	FORS-08453

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	41	Reynaldo et al., J. Mol. Biol. 97: 511-520 (2000)	
	42	Richards et al., Genetics in Medicine, 4:379-391 (2002)	
	43	Makowski et al., Annals of Clinical 7 Laboratory Science, 33:243-250 (2003)	
	44	Strom et al., Genetics in Medicine, 4:289-296 (2002)	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.